

REMARKS

Reconsideration of the allowability of the present application is requested respectfully. Applicants request that the Examiner reconsider and withdraw the finality of the present Office Action. The present application was filed as an RCE on December 13, 2004 and claims 1 and 25 were amended at the time of filing the RCE. Based on these claim amendments and the new manner in which the Examiner has applied the previously cited art, the present final rejection is improper.

Status of the Claims

Claims 1 to 31 were acted upon by the Examiner in the Office Action dated March 9, 2005. Claims 1 to 31 have been rejected. Claims 2 to 24 have been amended. Claim 1 has been canceled. No claims have been added. Accordingly, claims 2 to 31 are presented for examination.

Summary of the Examiner's Action**Claim Rejections**

Claims 2 to 6, 22, and 25 to 28 stand rejected under 35 U.S.C. §102(a), as being anticipated by Crespo (WO 97/33975, wherein the English version is US 6,248,588).

Claims 6 to 17, 22 to 26, and 29 to 31 stand rejected under 35 U.S.C. §103(a), as being unpatentable over Crespo in view of Engler (US 2003/0211598).

Claims 2 to 31 stand rejected under 35 U.S.C. §103(a), as being unpatentable over Crespo taken with Engler and further in view of Rolland (US 6,040,295) or Sene (WO 98/02522, wherein its English version is US 6,451,256).

Applicants respectfully traverse the Examiner's rejection.

Discussion**Amendments to the Claims**

Applicants have canceled claim 1 and amended claims 2 to 24 to depend directly or indirectly from claim 25. As claim 25 is a method claim, claims 2 to 24 have been amended to recite "The method" rather than "The composition". Support for these amendments is found throughout the application.

Discussion of the Section 102(a) Rejections

Claims 2 to 6, 22, and 25 to 28 have been rejected under 35 U.S.C. §102(a) as being anticipated by Crespo (WO 97/33975, wherein the English version is US 6,248,588).

Applicants respectfully traverse the rejection.

All claims directed to compositions have been canceled or amended to be directed to methods. Accordingly, the relevance of Crespo is determined by whether Crespo discloses “a method for preparing a stabilized recombinant adenovirus vector formulation” as recited by claim 25. As has been argued previously in the Reply dated December 13, 2004, applicants respectfully submit that Crespo does not disclose any information related to “recombinant adenovirus vectors”, but rather only discloses cryopreservation of viral particles.

The examiner has asserted that “It is well-established in the prior art that replication defective and/or recombinant adenovirus vectors are the same as adenoviral particles” (page 4 of the present Action). Applicants respectfully traverse this assertion.

The present application consistently uses the phrase “viral particles and viral vectors”. Clearly, applicants define particles and vectors as two different entities. Accordingly, based on the present application, recombinant adenovirus vectors are not the same as adenoviral particles.

In addition, applicants are unaware of any publication wherein the term “viral particle” is used to refer to a viral vector comprised of DNA or RNA. “Viral particle” is always used to refer to DNA/RNA surrounded by a protein envelope or coat. A viral particle is never the DNA/RNA alone.

The term “viral vector” is sometimes used to refer to both viral particles and viral DNA/RNA. It would not be incorrect to suggest that both viral particles and viral DNA/RNA could be considered species of the genus of viral vectors. However, as noted above, applicants have defined the terms to be mutually exclusive: viral particles and viral vectors refer to different entities.

Furthermore, it is important to determine how Crespo uses the terms “viral particle”. As noted in the Reply dated December 13, 2004, Crespo discloses medium for the cryopreservation of “biological materials”, including “viral particles”. The term “viral vector” does not appear anywhere in Crespo. Indeed the term “vector” does not appear. In view of the previous arguments and the fact that no where in the art does the term “viral particle” refer to naked DNA/RNA, applicants submit that Crespo does not disclose methods of preparing adenoviral

vector formulations and does not anticipate the presently claimed invention. If the Examiner wishes to maintain the present rejections in view of Crespo, applicants respectfully request that the Examiner identify examples of the use of the term "viral particle" as meaning naked DNA/RNA in the prior art.

As the presently claimed invention is directed to methods of preparing adenoviral vector formulations, and Crespo does not disclose such methods, applicants respectfully request that the rejection of claims 2 to 6, 22, and 25 to 28 under 35 U.S.C. §102(a) as being anticipated by Crespo be withdrawn.

The 35 U.S.C. §103(a) Rejections

Claims 6 to 17, 22 to 26, and 29 to 31 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crespo in view of Engler et al. (US 2003/0211598).

Engler et al. discloses buffers comprising a detergent or ethanol. Engler et al. has been cited for disclosure of Tris buffers. Crespo has been cited based on the Examiner's assertion that Crespo discloses compositions for the preservation of adenoviral vectors. The Examiner asserts that the combination of Crespo and Engler et al. render the presently claimed invention obvious.

Applicants respectfully traverse the rejection. With regard to a *prima facie* obviousness rejection the MPEP §2143 states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Accordingly, a proper *prima facie* case of obviousness requires three steps: 1) providing a suggestion or motivation to combine the references; 2) providing a reasonable expectation that the combination will be successful; and 3) providing a combination that teaches all of the claim limitations. Steps 1) and 2) must be found in the prior art. Applicant submits that the present rejection has not satisfied any of these requirements.

For the reasons noted above, Crespo does not disclose methods of preparing adenoviral vector formulations. The teachings of Engler et al. provide no basis to overcome the deficiencies

of Crespo. Accordingly, the Examiner has not satisfied the third requirement of teaching or suggesting all the claim limitations.

Accordingly, the Examiner has not satisfied one of the requirements of a *prima facie* case of obviousness. As such, applicants respectfully request that the rejection of claims 6 to 17, 22 to 26, and 29 to 31 under 35 U.S.C. § 103(a) as being unpatentable over Crespo in view of Engler et al. be withdrawn.

Claims 1 to 31 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Crespo taken with Engler et al. and further in view of Rolland et al. (US 6,040,295) and Sene (WO 98/02522, wherein the English version is US 6,451,256).

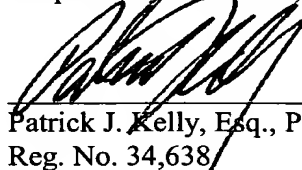
Applicants respectfully traverse the rejection.

Rolland et al. discloses compositions and methods for enhancing the uptake of nucleic acids by cells or organisms. Sene discloses methods for preserving viral particles in aqueous solution.

For the reasons noted above, that Crespo does not disclose methods of preparing adenoviral vector formulations. Rolland et al. and Sene provide no basis to overcome these deficiencies. Accordingly, applicants respectfully request that the rejection of claims 1 to 31 under 35 U.S.C. § 103(a) as being unpatentable over Crespo taken with Engler et al. and further in view of Rolland et al. and Sene be withdrawn.

A favorable action on the merits is requested respectfully. A Petition for a one-month extension of time, from June 9, 2005 to July 11, 2005 (July 9 being a Saturday), is enclosed.

Respectfully submitted,



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